DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 29 2000 1105 '00 APR 10 A9:56

Robert C. Mace, Manager
Quality Assurance and Regulatory Affairs
Pace Medical, Inc.
391 Totten Pond Road
Waltham, Massachusetts 02451

Re: 00P-0443

Dear Mr. Mace:

This responds to your citizen petition, dated January 14, 2000, concerning your firm's Model 4220 sterile disposable surgical extension cable. The cable is used to connect the pins of implanted pacemaker leads within a sterile surgical field to a remotely-placed, non-sterile pacing analyzer. Your petition requested an amendment of the Performance Standard for Electrode Lead Wires and Patient Cables (21 CFR 898) to exempt from the performance standard all lead wires and cables that are intended for use under the direct supervision of a physician. Alternatively, your petition requests an exemption or variance from the performance standard, as it applies to your Model 4220 cable.

You presented several arguments in support of your petition. You noted that pacing analyzers are battery powered and are used by physicians rather than minimally trained personnel. You also cited the advantage of a universally compatible male pin connectors, and the need for continued connection to heart wires that are exempted from the performance standard. You noted that your device is CE marked, and cited excessive cost in converting to a protected configuration. Finally, you argued that new unnecessary risks are created because of the need to have the correct cable available (e.g., for use with exempted heart wires versus non-exempted applications).

I am denying your requested amendment to the performance standard, and I am also denying your requested exemption / variance for the following reasons:

- Your arguments concerning excessive cost are not compelling. The cost of conversion was considered when the performance standard was first proposed in 1995, and was again considered in the final rule published in 1997. Manufacturers and users of pacing analyzers have been given three years to make their conversion to minimize the cost implications.

- You have presented no specific information concerning the relative costs of protected versus unprotected cable connectors. Protected connector designs are readily available

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- from many sources. Absent information to the contrary, we do not believe that they are significantly more expensive than exposed 2 mm pins.

- Pacing analyzers and other devices currently in use in hospitals will need to be converted via adapters to accept cables that comply with the performance standard. FDA is aware of several such adapters, available from multiple sources, for use with external pacing generators and analyzers. An adapter needs to be secured to the device in such a way that the adapter cannot be inadvertently removed when the cable is disconnected. Easy removal of the adapter with the cable could convert a compliant cable back to an unsafe configuration, thus defeating the safety intent of the performance standard. FDA has generally advised manufacturers that the adapter should either be permanently attached to the device, or removable only by use of a tool. One such available design locks the adapter securely into a 2 mm socket in the device, and can accept both a shrouded 2mm pin and an exposed 2mm pin. Such an adapter, if used to convert the pacing generator or analyzer, would allow connection to a compliant cable, while maintaining a capability to accept an FDA exempted heart wire, if needed.

- In some cases, adapters may be attached via a thumbscrew, collet or chuck on the device that is hand-tightened to secure the adapter in place. While not permanent, such a connection is considered by FDA to meet the intent of the performance standard if its removal requires a conscious decision and action by the user, and would involve more than simply pulling out the cable. Therefore, a user facility can routinely use an extension cable that meets the performance standard, but in an emergency can still remove the adapter for use with an exempted heart wire. We do not believe this creates any new risk to the patient.

- Note that the end of your cable nearest the patient is not subject to the performance standard. The alligator clips can continue to connect to exempted heart wires and permanent pacemaker lead wires, and they are not impacted by the connector design at the other end of the cable.

- At the end remote from the patient, your cable has exposed 2 mm pins, which when not connected to the analyzer, can be mistakenly plugged into an electrical line power source, or can be electrically shorted to a grounded table or bed. Two mm pins fit easily into wall outlets and power cords and are the principle reason for having the performance standard.

- The interchangeability of universally compatible exposed 2mm male connectors was one of the contributing factors in the last electrocution accident that occurred in 1993. That is a primary reason why the performance standard is applicable to all devices, rather than just those that have been directly implicated in accidents.

- The fact that your pacing analyzer is battery powered is irrelevant, because it is when the cable is not connected to the analyzer that it presents an electrical safety risk.

cc: HFA-305 (Docket #00P-0443)
HFA-224
HFR-NE200
HFZ-1
HFZ-3
HFZ-15 (JSheehan, MHanna, Files)
HFZ-141 (RWalchle)
HFZ-300 (r/f, binder)
HFZ-305 (Precedent Correspondence)
HFZ-340 (SCrumpler, Files)
HFZ-341
HFZ-450 (BZimmerman)
Draft:KABerthold:3/3/2000
Redraft:ESCrumpler:3/20/2000
Review:CEUldriks:3/22/00
f/t:cfrye:3/22/00 (citizen petition-pace medical)
Doc. Track # 82356